K093781

newdeal®
An Integra LifeSciences Company

JAN 22 2010

SPECIAL 510(k) SUMMARY

Modified Newdeal HALLU® PLATES

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Date Summary was prepared:

December 7, 2009

K093781

Name of the device:

Proprietary Name:	Newdeal HALLU® Plates
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030)
Device Product Code:	HRS
Classification Panel:	Orthopedic

Substantial Equivalence:
The modified HALLU® PLATES is substantially equivalent to the commercially marketed devices, HALLU® PLATES (K021626) and HALLU®-LOCK PLATES (K083154).

Device Description:
The Newdeal HALLU® PLATES is a low profile Titanium plate dedicated to first metatarso-phalangeal arthrodesis. The system includes both HALLU®-FIX C plates as well as HALLU®-FIX S plates. The plates are used in conjunction with Newdeal SNAP-OFF® screws.

Indications for Use:
The HALLU® PLATES is intended to be implanted for fixation of fractures, osteotomies or arthordesis of the first metatarso-phalangeal joint, including cases of:

- Hallux rigidus
- Severe hallux valgus (IM angle >20° and HV angle >40°)
- Deformity from rheumatoid arthritis
- Failed previous surgical procedure
- Traumatic arthritis
- Neuromuscular instability.

These are the same indications for use as previously cleared for the unmodified device, HALLU® PLATES (K021626).

Additionally, during the review of 510(k) K083154, Newdeal HALLU®-LOCK PLATES, the inclusion of the following statement was requested by the FDA:

> *Addition of a QWIX® fixation screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.*

In order to be consistent, the following similar statement will also be included in the indications for use for this proposed 510(k) of the modified HALLU® PLATES.

- Addition of a screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.

The statement has now been amended from "addition of a QWIX® fixation screw" to "addition of a screw" to generalize the type of screw utilized to cross the joint, allowing for surgeon preference.

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Testing and Test Results:
Mechanical tests have been carried out. Results have shown that the mechanical properties of the modified HALLU® PLATES are equivalent to the properties of the unmodified devices, HALLU® PLATES (K021626) and HALLU®-LOCK PLATES (K083154).

Conclusion
The modified HALLU® PLATES is substantially equivalent to commercially marketed devices, HALLU® PLATES (K021626) and HALLU®-LOCK PLATES (K083154).

The modifications do not change the intended use or fundamental scientific technology of the device and do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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% Integra LifeSciences Corporation
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JAN 22 2010

Re: K093781
Trade/Device Name: Newdeal HALLU Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 5, 2010
Received: January 6, 2010

Dear Mr. Beier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093781

Device Name: Newdeal HALLU® PLATES

Indications For Use:

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- Neuromuscular instability

Addition of a screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093781